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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,428	12/18/2000	Philip P.M. Finch	2537	3665

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EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,428

Applicant(s)

FINCH ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/26/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 31 recites “the thermal probe defining proximal and distal ends and having a guidable region adjacent the distal end thereof, the guidable region characterized by having sufficient rigidity to puncture and advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus.” However, nowhere in the specification other than amended claim 31 does it disclose that the guidable portion (in a distal region) of the thermal probe puncturing the annulus fibrosus. In fact the puncturing and introduction of the thermal probe into the annulus fibrosus is

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facilitated by the cannula (1) (which is exactly what the prior art discloses), see page 4, lines 4-7, 12-13 and 16-17, page 6, lines 3-7, page 7, line 20 through page 8, line 1.

In order to examine the claims 31-36, the examiner will interpret claim 31 as though the words “puncture and” in line 10 were not present. In other words, the guidable portion is simply advanced within the annulus fibrosus (as in claim 20).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 20-25, 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharkey et al. (USPN 6,126,682).

Regarding claim 20, Sharkey et al. disclose a method for relieving pain associated with an intervertebral disc having a disc nucleus pulposus and an outer annulus fibrous surrounding the nucleus pulposus, comprising; introducing a thermal transmitting element of a thermal probe (14) into the annulus fibrosus of the intervertebral disc, the thermal probe defining proximal and distal ends and having a guidable region (flexible distal portion) adjacent the distal end thereof, the guidable region characterized by having sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus; and supplying thermal energy from a thermal energy source to the thermal transmitting element ("energy source" of col. 4, lines 28-32, "energy delivery element" of col. 5, lines 62-65 and (18) in col. 15) to heat the annulus fibrous adjacent the transmitting element sufficiently to relieve pain associated with the intervertebral disc, see abstract and col. 4 and figures 1D and 4.

Regarding claims 21 and 22, Sharkey et al. disclose the claimed invention, see col. 10-14 and element (16) of figure 4.

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Regarding claims 23 and 24, Sharkey et al. disclose the claimed invention, see col. 4, lines 1-10 and figure 4.

Regarding claim 25, Sharkey et al. disclose the claimed invention, see col. 5, line 53 through col. 9, lines 37 and (12) in figure 4.

Regarding claims 29, 30, 35 and 36, Sharkey et al. disclose the claimed invention, see col. 15, lines 1-12 and col. 16, lines 49-67.

Regarding claims 31 and 32, Sharkey et al. disclose a method for relieving pain associated with an intervertebral disc, the intervertebral disc having a disc nucleus and all outer annulus surrounding the disc nucleus, the method comprising the steps of: accessing an intervertebral disc with a cannula; advancing a thermal probe having a heat transmitting region through the cannula into the intervertebral disc to position the heat transmitting region of the thermal probe in at least one of posterior, lateral and posterior-lateral areas of the annulus fibrous; and supplying thermal energy from a thermal energy source to the heat transmitting end region to heat the at least one area to treat pain associated with the intervertebral disc, wherein the step of accessing includes advancing a distal end of the cannula through the intervertebral disc to position the distal end within the annulus fibrous, see abstract and col. 4-14 and figures 1D and 4. It should be noted that the guidable region characterized by having sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted

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on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus, see figure 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (USPN 6,126,682) in view of Hertzmann et al. (USPN 5,084,043).

Regarding claims 26 and 33, Sharkey et al. disclose the claimed invention except for explicitly reciting that the cannula has an arcuate portion at the distal thereof. Hertzmann et al. disclose a method of treating spinal problems using an energy delivery means (132) and an arcuate or distally curved introducer/cannula "in situations where the patient's afflicted area is within the lumbar 5-sacrum 1 region of the vertebral column," see col. 7, lines 47-54 and figures 1 and 30B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Sharkey et al.,

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as taught by Hertzmann et al., to use an arcuate or distally curved introducer/cannula “in situations where the patient's afflicted area is within the lumbar 5-sacrum 1 region of the vertebral column.”

Regarding claims 27, 28 and 34, Sharkey et al. in view of Hertzmann et al. disclose the claimed invention.

Response to Amendment

The amendment, filed 11/26/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

“the guidable region characterized by having sufficient rigidity to puncture and advance within the annulus fibrosus.”

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments filed 11/26/2005 have been fully considered but they are not persuasive. Applicant asserts on page 11, line 12 of response that the catheter of Sharkey et al. "has insufficient penetration ability to be advanceable out through the annulus fibrosus under the applied force (column 4, lines 2-10)." The examiner can find no reference of this kind in the stated columns and lines. However in col. 11, lines 21-22 of Sharkey et al. it is stated that "the distal portion 28 of intradiscal section 16 is designed to be incapable of piercing the annulus fibrosus 122," which lends support to Applicant main point which is that guidable portion of the thermal probe disclosed by Sharkey et al. is not capable of, is not intended to and does not puncture the annulus fibrosus. To this assertion, the examiner agrees.

However, claim 20 only recites that the guidable region is "characterized by having sufficient rigidity to advance within the annulus fibrosus," to which the examiner points out that the guidable region of the thermal probe disclosed by Sharkey et al. is most definitely rigid enough to advance within the annulus fibrosus since that is exactly what is done with the thermal probe disclosed by Sharkey et al. (see for example, figure 4).

Regarding the arguments directed to claim 31, the examiner offers the same exact rebuttal as given for claim 20.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
February 22, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER